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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ESPERION THERAPEUTICS, INC., Plaintiff, v. AUROBINDO PHARMA LIMITED and APITORIA PHARMA PRIVATE LIMITED Defendants.	C.A. No. 24-cv-06348 (JXN)(CLW) ELECTRONICALLY FILED

DEFENDANTS AUROBINDO PHARMA LIMITED AND APITORIA PHARMA PRIVATE LIMITED'S ANSWER TO FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Defendants Aurobindo Pharma Limited ("Aurobindo Pharma") and Apitoria Pharma Private Limited ("Apitoria") (collectively, "Aurobindo"), by their counsel, hereby respond to the allegations set forth in Plaintiff Esperion Therapeutics, Inc's First Amended Complaint ("Complaint") against Defendant. The headings in the Complaint are copied herein for convenience only, and any allegations in such headings are denied.

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Aurobindo denies all allegations in Plaintiff's

Complaint except those specifically admitted below.

1. This is an action for patent infringement by Esperion Therapeutics, Inc. ("Esperion") under the patent laws of the United States, Title 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, against Defendants Aurobindo Pharma Limited and Apitoria Pharma Private Limited (collectively, "Aurobindo"). This action arises out of Aurobindo's submission of Abbreviated New Drug Application ("ANDA") No. 219349 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of NEXLETOL® prior to the expiration of U.S. Patent Nos. 11,760,714, 11,613,511, and 11,926,584 (collectively, the "Asserted Patents").

ANSWER: Aurobindo admits that this action purports to arise under the United States Patent Laws, Title 35, United States Code § 100 et seq., and under the Declaratory Judgment Act, 28 U.S.C. § 2201 and 2202. Aurobindo admits that Plaintiff purports to seek relief from alleged infringement by Aurobindo of U.S. Patent Nos. 11,760,714 ("the '714 patent"), 11,613,511 ("the '511 patent"), and 11,926,584 ("the '584 patent") (collectively, the "Asserted Patents") listed in the Orange Book for Plaintiff's Nexletol® (bempedoic acid) drug product. Aurobindo also admits that Aurobindo Pharma filed ANDA No. 219349 ("Aurobindo's ANDA"), which seeks FDA approval to market its generic version of bempedoic acid prior to expiration of the Asserted Patents. Aurobindo denies any remaining allegations in this paragraph.

PARTIES

2. Plaintiff Esperion is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 3891 Ranchero Drive, Suite 150 Ann Arbor, MI 48108.

ANSWER: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the Complaint and therefore denies them.

3. Upon information and belief, Defendant Aurobindo Pharma Limited ("Aurobindo Pharma") is a corporation organized and existing under the laws of India, having a principal place of business at Galaxy, Floors: 22-24, Plot No. 1, Survey No. 83/1, Hyderabad Knowledge City, Raidurg Panmaktha, Ranga Reddy District, Hyderabad, Telangana, 500032, India.

ANSWER: Admitted.

4. Upon information and belief, Aurobindo Pharma is a pharmaceutical company that engages in the manufacture, marketing, or sale of pharmaceutical products, including generic drug products manufactured and sold pursuant to approved ANDAs.

ANSWER: Paragraph 4 states a legal conclusion to which no response is required. To the extent an answer is required, Aurobindo admits that it develops and manufactures in India high-quality generic pharmaceutical products, among other things. Aurobindo denies any remaining allegations of this paragraph.

5. Upon information and belief, Aurobindo Pharma directly or through its affiliates develops, markets, and sells drug products throughout the United States, including in the state of New Jersey.

ANSWER: Paragraph 5 states a legal conclusion to which no response is required. To the extent an answer is required, Aurobindo admits that it develops and manufactures in India high-quality generic pharmaceutical products, among other things, and that some of its products are ultimately used by consumers in the United States. Aurobindo denies any remaining allegations of this paragraph.

6. Upon information and belief, Apitoria Pharma Private Limited ("Apitoria"), formerly known as Auro Pharma India Private Limited, is a corporation organized and existing under the laws of India, having a principal place of business at Galaxy, Floors: 22-24, Plot No. 1, Survey No. 83/1, Hyderabad Knowledge City, Panmaktha, Rai Durg, Hyderabad, 500032, India.

ANSWER: Admitted.

7. Upon information and belief, Apitoria is a pharmaceutical company that engages in the manufacture, marketing, or sale of pharmaceutical products, including generic drug products manufactured and sold pursuant to approved ANDAs.

ANSWER: Paragraph 7 states a legal conclusion to which no response is required. To the extent an answer is required, Aurobindo admits that it develops and manufactures in India high-

quality generic pharmaceutical products, among other things. Aurobindo denies any remaining allegations of this paragraph.

8. Upon information and belief, Apitoria directly or through its affiliates markets and sells drug products throughout the United States, including in the state of New Jersey.

ANSWER: Paragraph 8 states a legal conclusion to which no response is required. To the extent an answer is required, Aurobindo admits that it develops and manufactures in India high-quality generic pharmaceutical products, among other things, and that some of its products are ultimately used by consumers in the United States. Aurobindo denies any remaining allegations of this paragraph.

9. Upon information and belief, Apitoria is the holder of FDA Drug Master File No. 38811 for Bempedoic Acid.

ANSWER: Paragraph 9 states a legal conclusion to which no response is required. To the extent an answer is required, Aurobindo admits that the list of Drug Master Files located at https://www.fda.gov/drugs/drug-master-files-dmfs/list-drug-master-files-dmfs contains an entry for DMF No. 38811 associated with Apitoria Pharma Private Ltd. Aurobindo denies any remaining allegations of this paragraph.

10. Upon information and belief, Apitoria is a wholly-owned subsidiary of Aurobindo Pharma.

ANSWER: Admitted.

11. Upon information and belief, Aurobindo Pharma directs or controls the operations, management, and activities of Apitoria.

ANSWER: Paragraph 11 states a legal conclusion to which no response is required. Aurobindo denies any remaining allegations of this paragraph.

12. Upon information and belief, Aurobindo Pharma and Apitoria are agents of each other and/or operate in concert as integrated parts of the same business group.

ANSWER: Paragraph 12 states a legal conclusion to which no response is required. Aurobindo denies any remaining allegations of this paragraph.

13. Upon information and belief, Aurobindo Pharma and Apitoria work in concert on the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products for the United States market, including New Jersey.

ANSWER: Paragraph 13 states a legal conclusion to which no response is required. Aurobindo denies any remaining allegations of this paragraph.

14. Upon information and belief, Aurobindo Pharma and Apitoria working in concert prepared and submitted ANDA No. 219349 seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of a generic version of NEXLETOL® (the "Aurobindo ANDA Product") prior to the expiration of the Asserted Patents.

ANSWER: Paragraph 14 states a legal conclusion to which no response is required. To the extent an answer is required, Aurobindo admits that Aurobindo Pharma filed Aurobindo's ANDA, which seeks FDA approval to market its generic version of bempedoic acid prior to expiration of the Asserted Patents. Aurobindo denies any remaining allegations of this paragraph.

15. Upon information and belief, Aurobindo Pharma and Apitoria working in concert developed the Aurobindo ANDA Product.

ANSWER: Paragraph 15 states a legal conclusion to which no response is required. To the extent an answer is required, Aurobindo admits that Aurobindo Pharma filed Aurobindo's ANDA, which seeks FDA approval to market its generic version of bempedoic acid. Aurobindo denies any remaining allegations of this paragraph.

16. Upon information and belief, Aurobindo Pharma and Apitoria working in concert seek regulatory approval from the FDA to market and sell the Aurobindo ANDA Product throughout the United States, including in New Jersey.

ANSWER: Paragraph 16 states a legal conclusion to which no response is required. To the extent an answer is required, Aurobindo admits that Aurobindo Pharma filed Aurobindo's

ANDA, which seeks FDA approval to market its generic version of bempedoic acid in the United States, including in New Jersey. Aurobindo denies any remaining allegations of this paragraph.

> 17. Upon information and belief, Aurobindo Pharma and Apitoria working in concert intend to obtain approval for Aurobindo Pharma and Apitoria's ANDA No. 219349, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import the Aurobindo ANDA Product in the United States, including in New Jersey.

ANSWER: Paragraph 17 states a legal conclusion to which no response is required. To the extent an answer is required, Aurobindo admits that Aurobindo Pharma filed Aurobindo's ANDA, which seeks FDA approval to market its generic version of bempedoic acid in the United States, including in New Jersey. Aurobindo denies any remaining allegations of this paragraph.

> 18. Upon information and belief, Aurobindo Pharma regularly works in concert with its wholly-owned U.S. subsidiaries, including Aurobindo Pharma USA, Inc. and Aurobindo Pharma Limited, Inc. to commercially manufacture, use, offer for sale, sell, and/or import pharmaceutical products in New Jersey.

ANSWER: Paragraph 18 states a legal conclusion to which no response is required. To the extent an answer is required, Aurobindo admits that Aurobindo Pharma filed Aurobindo's ANDA, which seeks FDA approval to market its generic version of bempedoic acid in the United States, including in New Jersey. Aurobindo denies any remaining allegations of this paragraph.

> 19. Upon information and belief, Aurobindo Pharma USA, Inc. is a corporation with its principal place of business at 279 Princeton Hightstown Road, East Windsor, NJ 08520, is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Entity ID No. 0100921223, and is registered with the State of New Jersey's Department of Health as a drug wholesaler and manufacturer operating in New Jersey under Registration No. 5003120.

ANSWER: Aurobindo Pharma USA, Inc. is not a named defendants is this action and accordingly no response is required.

> 20. Upon information and belief, Aurobindo Pharma Limited, Inc. is a corporation with its principal place of business at 666 Plainsboro Rd., Plainsboro, NJ, 08536 and is registered with the State of New Jersey's Division of Revenue and

Enterprise Services as a business operating in New Jersey under Business Entity ID No. 0100904116.

ANSWER: Aurobindo Pharma Limited, Inc. is not a named defendants is this action and accordingly no response is required.

JURISDICTION AND VENUE

21. This action arises under the patent laws of the United States of America, 35 U.S.C. § 100 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 21 states a legal conclusion to which no response is required. Aurobindo will not contest that this Court has subject-matter jurisdiction for the limited purpose of this action only. To the extent an answer is required, Aurobindo denies any remaining allegations of this paragraph.

22. This Court has personal jurisdiction over Aurobindo Pharma because, among other things, it has committed, aided, abetted, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) by preparing and filing portions of its ANDA No. 219349 in New Jersey, and it intends to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b), and/or (c) in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Esperion. For example, upon information and belief, following approval of ANDA No. 219349, Aurobindo Pharma will make, use, import, sell, and/or offer for sale the Aurobindo ANDA Product in the United States, including in New Jersey, prior to the expiration of the Asserted Patents.

ANSWER: Paragraph 22 states a legal conclusion to which no response is required. Aurobindo Pharma will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Aurobindo denies any remaining allegations of this paragraph.

23. This Court also has personal jurisdiction over Aurobindo Pharma because, among other things, this action arises from Aurobindo Pharma's actions directed toward New Jersey, and because, upon information and belief, Aurobindo Pharma has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey, including by, among other things, (1) intentionally marketing and providing its generic

> pharmaceutical products to residents of New Jersey; (2) enjoying substantial income from New Jersey; and (3) working in concert to develop and market pharmaceutical products, including in New Jersey, with its subsidiaries Aurobindo Pharma USA and Aurobindo Pharma Limited, Inc., who are registered to do business and sell pharmaceutical products in New Jersey. Aurobindo Pharma has therefore purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled [sic.] into court here.

ANSWER: Paragraph 23 states a legal conclusion to which no response is required. Aurobindo Pharma will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Aurobindo denies any remaining allegations of this paragraph.

> 24. In addition, this Court has personal jurisdiction over Aurobindo Pharma because, among other things, upon information and belief, (1) Aurobindo Pharma filed its ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, sale, and/or offer for sale of the Aurobindo ANDA Product in the United States, including in New Jersey, and (2) upon approval of the ANDA, Aurobindo Pharma will market, distribute, offer for sale, sell, and/or import the Aurobindo ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of the Aurobindo ANDA Product in New Jersey. Upon information and belief, upon approval of Aurobindo Pharma's ANDA, the Aurobindo ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have substantial effects on New Jersey and lead to foreseeable harm and injury to Esperion.

ANSWER: Paragraph 24 states a legal conclusion to which no response is required. Aurobindo Pharma will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Aurobindo denies any remaining allegations of this paragraph.

> 25. This Court also has personal jurisdiction over Aurobindo Pharma because Aurobindo Pharma regularly engages in patent litigation in this forum, and affirmatively avails itself of the jurisdiction of this Court by filing counterclaims in this District and by being sued in this District without challenging personal jurisdiction, including in at least *Axsome Malta Ltd. v. Aurobindo Pharma USA, Inc.*, C.A. No. 24-cv-04002, Dkt. No. 11 (D.N.J. filed Feb. 5, 2024); *Bausch Health Ireland Limited v. Aurobindo Pharma Limited*, C.A. No. 23-cv-00170, Dkt. No. 16, (D.N.J. filed Jul. 5, 2023); and *Medicure International, Inc. v. Aurobindo Pharma Limited*, C.A. No. 21-cv-17534, Dkt. No. 6 (D.N.J. filed Oct. 15, 2021).

ANSWER: Paragraph 25 states a legal conclusion to which no response is required. Aurobindo Pharma will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Aurobindo denies any remaining allegations of this paragraph.

26. This Court also has personal jurisdiction over Aurobindo Pharma because, upon information and belief, Aurobindo Pharma worked with its counsel in New Jersey, Pergament & Cepeda, LLP, to prepare the certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification") regarding the Asserted Patents for ANDA No. 219349, and designated, pursuant to 21 C.F.R. § 314.95(c)(9), its New Jersey counsel, Pergament & Cepeda, LLP, to be its agent in the United States authorized to accept service of process in New Jersey on Aurobindo Pharma's behalf in relation to its ANDA No. 219349.

ANSWER: Paragraph 26 states a legal conclusion to which no response is required. Aurobindo Pharma will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Aurobindo denies any remaining allegations of this paragraph.

27. Based on the foregoing systematic and continuous contacts with New Jersey, Aurobindo Pharma is subject to specific personal jurisdiction in New Jersey.

ANSWER: Paragraph 27 states a legal conclusion to which no response is required. Aurobindo Pharma will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Aurobindo denies any remaining allegations of this paragraph.

28. Upon information and belief, Aurobindo Pharma's contacts with other states of the United States are no greater than its contacts with New Jersey. Therefore, to the extent Aurobindo Pharma denies that this Court has personal jurisdiction over it because of its systematic and continuous contacts with New Jersey, this Court also has personal jurisdiction over Aurobindo Pharma pursuant to Federal Rule of Civil Procedure 4(k)(2)(A) because Aurobindo Pharma is not subject to the general jurisdiction of the courts of any state, and based on its contacts with the United States as a whole. Relatedly, in its Notice Letter (defined below) to Esperion, Aurobindo Pharma represented that Pergament & Cepeda, LLP is the agent for service of process "[p]ursuant to 21 C.F.R. § 314.95(c)(9)," which applies "[i]f the applicant does not reside or have a place of business in the United States."

ANSWER: Paragraph 28 states a legal conclusion to which no response is required. Aurobindo Pharma will not contest that this Court has personal jurisdiction for the limited purpose

of this action only. Aurobindo denies any remaining allegations of this paragraph.

29. This Court has personal jurisdiction over Apitoria because, among other things, it has committed, aided, abetted, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) by preparing and filing portions of ANDA No. 219349 in New Jersey, and intends to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b), and/or (c) in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Esperion. For example, upon information and belief, following approval of ANDA No. 219349, Apitoria, working in concert with Aurobindo Pharma, will make, use, import, sell, and/or offer for sale the Aurobindo ANDA Product in the United States, including in New Jersey, prior to the expiration of the Asserted Patents.

ANSWER: Paragraph 29 states a legal conclusion to which no response is required. Apitoria will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Aurobindo denies any remaining allegations of this paragraph.

30. This Court also has personal jurisdiction over Apitoria because, among other things, this action arises from Apitoria's actions directed toward New Jersey, and because, upon information and belief, Apitoria has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey, including by, among other things, (1) intentionally marketing and providing its generic pharmaceutical products to residents of New Jersey; (2) enjoying substantial income from New Jersey; and (3) working in concert with its affiliates Aurobindo Pharma USA, Inc. and Aurobindo Pharma Limited, Inc. to develop and market pharmaceutical products, including in New Jersey. Apitoria has therefore purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled [sic.] into court here.

ANSWER: Paragraph 30 states a legal conclusion to which no response is required. Apitoria will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Aurobindo denies any remaining allegations of this paragraph.

31. In addition, this Court has personal jurisdiction over Apitoria because, among other things, upon information and belief, (1) Apitoria working in concert with Aurobindo Pharma filed its ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, sale, and/or offer for sale of the Aurobindo ANDA Product in the United States, including in New Jersey, and (2) upon approval of the ANDA, Apitoria working in concert with Aurobindo Pharma will market, distribute, offer for sale, sell, and/or import the Aurobindo ANDA

> Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of the Aurobindo ANDA Product in New Jersey. Upon information and belief, upon approval of ANDA No. 219349, the Aurobindo ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have substantial effects on New Jersey and lead to foreseeable harm and injury to Esperion.

ANSWER: Paragraph 31 states a legal conclusion to which no response is required. Apitoria will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Aurobindo denies any remaining allegations of this paragraph.

> 32. Based on the foregoing systematic and continuous contacts with New Jersey, Apitoria is subject to specific personal jurisdiction in New Jersey.

ANSWER: Paragraph 32 states a legal conclusion to which no response is required. Apitoria will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Aurobindo denies any remaining allegations of this paragraph.

> 33. Upon information and belief, Apitoria's contacts with other states of the United States are no greater than its contacts with New Jersey. Therefore, to the extent Apitoria denies that this Court has personal jurisdiction over it because of its systematic and continuous contacts with New Jersey, this Court also has personal jurisdiction over Apitoria pursuant to Federal Rule of Civil Procedure 4(k)(2)(A) because Apitoria is not subject to the general jurisdiction of the courts of any state, and based on its contacts with the United States as a whole.

ANSWER: Paragraph 33 states a legal conclusion to which no response is required. Apitoria will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Aurobindo denies any remaining allegations of this paragraph.

> 34. For at least the above reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, it would not be unfair or unreasonable for Aurobindo Pharma and Apitoria to litigate this action in this Court, and Aurobindo Pharma and Apitoria are subject to personal jurisdiction in New Jersey.

ANSWER: Paragraph 34 states a legal conclusion to which no response is required. Aurobindo Pharma and Apitoria will not contest that this Court has personal jurisdiction for the

limited purpose of this action only. Aurobindo denies any remaining allegations of this paragraph.

35. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b). *In re HTC Corp.*, 889 F.3d 1349, 1354 (Fed. Cir. 2018).

ANSWER: Paragraph 35 states a legal conclusion to which no response is required. Aurobindo will not contest that venue is proper in this Court for the limited purpose of this action only. Aurobindo denies any remaining allegations of this paragraph.

36. Venue is proper in this Court as to Aurobindo Pharma under 28 U.S.C. §§ 1391(b) and (c) and 1400(b), because, upon information and belief, Aurobindo Pharma is a corporation organized under the laws of India, is not a resident of the United States, and thus may be sued in any jurisdiction. 28 U.S.C. §§ 1391(c)(3); *HTC*, 889 F.3d at 1354.

ANSWER: Paragraph 36 states a legal conclusion to which no response is required. Aurobindo Pharma will not contest that venue is proper in this Court for the limited purpose of this action only. Aurobindo Pharma denies any remaining allegations of this paragraph.

37. Venue is also proper in this Court as to Aurobindo Pharma because Aurobindo Pharma has a regular and established place of business in New Jersey at least because, upon information and belief, it: (1) has sought approval from the FDA to market and sell Aurobindo's proposed generic NEXLETOL® product in New Jersey; and (2) has engaged in regular and established business contacts with New Jersey by, among other things, marketing, making, shipping, using, offering to sell, or selling pharmaceutical products in New Jersey, and deriving substantial revenue from such activities.

ANSWER: Paragraph 37 states a legal conclusion to which no response is required. Aurobindo Pharma will not contest that venue is proper in this Court for the limited purpose of this action only. Aurobindo denies any remaining allegations of this paragraph.

38. Venue is proper in this Court as to Apitoria under 28 U.S.C. §§ 1391(b) and (c) and 1400(b), because, upon information and belief, Apitoria is a corporation organized under the laws of India, is not a resident of the United States, and thus may be sued in any jurisdiction. 28 U.S.C. §§ 1391(c)(3); *HTC*, 889 F.3d at 1354.

ANSWER: Paragraph 38 states a legal conclusion to which no response is required. Apitoria will not contest that venue is proper in this Court for the limited purpose of this action

only. Aurobindo denies any remaining allegations of this paragraph.

39. Venue is also proper in this Court as to Apitoria because Apitoria has a regular and established place of business in New Jersey at least because, upon information and belief, it: (1) has sought approval from the FDA to market and sell Aurobindo's proposed generic NEXLETOL® product in New Jersey; and (2) has engaged in regular and established business contacts with New Jersey by, among other things, marketing, making, shipping, using, offering to sell, or selling pharmaceutical products in New Jersey, and deriving substantial revenue from such activities.

ANSWER: Paragraph 39 states a legal conclusion to which no response is required. Apitoria will not contest that venue is proper in this Court for the limited purpose of this action only. Aurobindo denies any remaining allegations of this paragraph.

THE PATENTS-IN-SUIT

40. U.S. Patent No. 11,760,714 (the "'714 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on September 19, 2023. A true and correct copy of the '714 Patent is attached hereto as "Exhibit A."

ANSWER: Aurobindo admits that Exhibit A contains a copy of what purports to be the '714 patent and that bears the title "Methods of Making Bempedoic Acid and Compositions of the Same" and an issue date of September 19, 2023. Aurobindo denies that the '714 patent was "duly and legally issued." Aurobindo denies any remaining allegations in this paragraph.

41. Esperion is the assignee of, and holds all rights, title, and interest in the '714 Patent.

ANSWER: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 41 of the Complaint and therefore denies them.

42. The '714 Patent currently expires on June 19, 2040.

ANSWER: Paragraph 42 states a legal conclusion to which no response is required. To the extent an answer is required, the Electronic Orange Book lists the expiration date of the '714 Patent as June 19, 2040. Aurobindo Pharma denies any remaining allegations of this paragraph.

43. U.S. Patent No. 11,613,511 (the "'511 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on March 28, 2023. A true and correct copy of the '511 Patent is attached hereto as "Exhibit B."

ANSWER: Aurobindo admits that Exhibit B contains a copy of what purports to be the '511 patent and that bears the title "Methods of Making Bempedoic Acid and Compositions of the Same" and an issue date of March 28, 2023. Aurobindo denies that the '511 patent was "duly and legally issued." Aurobindo denies any remaining allegations in this paragraph.

44. Esperion is the assignee of, and holds all rights, title, and interest in the '511 Patent.

ANSWER: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 44 of the Complaint and therefore denies them.

45. The '511 Patent currently expires on June 19, 2040.

ANSWER: Paragraph 45 states a legal conclusion to which no response is required. To the extent an answer is required, the Electronic Orange Book lists the expiration date of the '511 Patent as June 19, 2040. Aurobindo denies any remaining allegations of this paragraph.

46. U.S. Patent No. 11,926,584 (the "'584 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on March 12, 2024. A true and correct copy of the '584 Patent is attached hereto as "Exhibit C."

ANSWER: Aurobindo admits that Exhibit C contains what purports to be a copy the '584 patent and that bears the title "Methods of Making Bempedoic Acid and Compositions of the Same" and an issue date of March 12, 2024. Aurobindo denies that the '584 patent was "duly and legally issued." Aurobindo denies any remaining allegations in this paragraph.

47. Esperion is the assignee of, and holds all rights, title, and interest in the '584 Patent.

ANSWER: Aurobindo is without knowledge or information sufficient to form a belief

as to the truth of the allegations in paragraph 47 of the Complaint and therefore denies them.

48. The '584 Patent currently expires on June 19, 2040.

ANSWER: Paragraph 48 states a legal conclusion to which no response is required. To the extent an answer is required, the Electronic Orange Book lists the expiration date of the '584 Patent as June 19, 2040. Aurobindo denies any remaining allegations of this paragraph.

49. All claims of the '714, '511 and '584 Patents are valid, enforceable, and not expired.

ANSWER: Paragraph 49 states a legal conclusion to which no response is required. Aurobindo admits that according to the Electronic Orange Book, the '714,'511, and '586 Patents are not expired. Aurobindo denies any remaining allegations of this paragraph.

ESPERION'S NEXLETOL PRODUCT

50. Esperion is a research-driven pharmaceutical company that discovers, develops, manufactures, and markets life-saving pharmaceutical products, including NEXLETOL®.

ANSWER: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 50 of the Complaint, except Aurobindo admits that the Electronic Orange Book lists "Esperion Therapeutics Inc." as an applicant holder for New Drug Application No. 211616 associated with the trade name NEXLETOL®. Aurobindo denies any remaining allegations of this paragraph.

51. Esperion is the holder of New Drug Application ("NDA") No. 211616, which was approved by the FDA on February 21, 2020, for the marketing and sale of bempedoic acid in the United States under the trade name "NEXLETOL®." Esperion sells NEXLETOL® in the United States pursuant to NDA No. 211616.

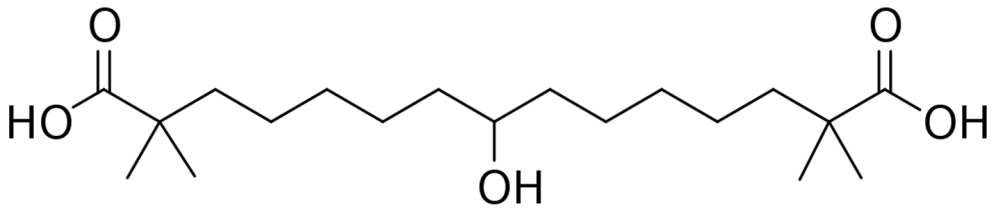
ANSWER: Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 51 of the Complaint, except Aurobindo admits that the Electronic Orange Book lists "Esperion Therapeutics Inc." as an applicant holder for the New

Drug Application No. 211616 associated with the trade name NEXLETOL®. Aurobindo denies any remaining allegations of this paragraph.

> 52. NEXLETOL® (bempedoic acid) is an adenosine triphosphate-citrate lyase (ACL) inhibitor indicated to 1) reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with established cardiovascular disease (CVD), or a high risk for a CVD event but without established CVD, and 2) as an adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).

ANSWER: Paragraph 52 states a legal conclusion to which no response is required. To the extent an answer is required, Aurobindo is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 52 of the Complaint and therefore denies them.

> 53. Bempedoic acid, the active pharmaceutical ingredient in NEXLETOL®, has the chemical name 8-hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid and has the following chemical structure:



ANSWER: Paragraph 53 states a legal conclusion to which no response is required. To the extent an answer is required, Aurobindo admits that the chemical name identified in the paragraph 53 corresponds to bempedoic acid. Aurobindo denies any remaining allegations of this paragraph.

> 54. The claims of the Asserted Patents cover NEXLETOL®.

ANSWER: Paragraph 54 states a legal conclusion to which no response is required. To the extent an answer is required, Aurobindo is without knowledge or information sufficient to form

a belief as to the truth of the allegations in paragraph 54 of the Complaint and therefore denies them.

55. The Asserted Patents have been listed in connection with NEXLETOL® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the "Orange Book."

ANSWER: Aurobindo admits that the Electronic Orange Book as of the date of the filing of this Answer lists the Asserted Patents for Plaintiff's Nexletol® (bempedoic acid) drug product.

AUROBINDO'S ANDA PRODUCT

56. By letter dated April 8, 2024, and received by Esperion via Federal Express on April 10, 2024 (the "Notice Letter"), Aurobindo notified Esperion that Aurobindo had submitted ANDA No. 219349 to the FDA for a generic version of NEXLETOL®.

ANSWER: Paragraph 56 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Aurobindo Pharma admits that on April 8, 2024, it sent a Notice Letter to Esperion Therapeutics, Inc. pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 notifying Esperion that it had filed patent certifications pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and § 314.94(a)(12)(i)(A)(4) of Title 21 of the CFR in support of Aurobindo's ANDA. Aurobindo denies any remaining allegations in this paragraph.

57. The First Notice Letter states that Aurobindo seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale of the Aurobindo ANDA product before the expiration of the '714 and '514 Patents. Upon information and belief, Aurobindo intends to – directly or indirectly – engage in the commercial manufacture, use, and/or sale of the Aurobindo ANDA product promptly upon receiving FDA approval to do so.

ANSWER: Paragraph 57 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Aurobindo Pharma admits that on April

8, 2024, it sent a Notice Letter to Esperion Therapeutics, Inc. pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 notifying Esperion that it had filed patent certifications with respect to the '714 and '511 patents pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and § 314.94(a)(12)(i)(A)(4) of Title 21 of the CFR in support of Aurobindo's ANDA. Aurobindo denies any remaining allegations in this paragraph.

58. By submitting ANDA No. 219349, Aurobindo has represented to the FDA that the Aurobindo ANDA Product has the same active ingredient, dosage form, and strength as NEXLETOL® and is bioequivalent to NEXLETOL®.

ANSWER: Paragraph 58 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Aurobindo Pharma's filing of an ANDA with the FDA is merely a technical act of infringement and does not carry with it any implications of infringement, contributory infringement, or inducement of infringement under 35 U.S.C. § 271(a), (b), and/or (c). Aurobindo denies any remaining allegations of this paragraph.

59. In the First Notice Letter, Aurobindo stated that ANDA No. 219349 includes a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '714 and '511 Patents. Aurobindo also contended that the '714 and '511 Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and/or sale of the Aurobindo ANDA Product.

ANSWER: Paragraph 59 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Aurobindo Pharma admits that on April 8, 2024, it sent a Notice Letter to Esperion Therapeutics, Inc. pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 and filed patent certifications with respect to the '714 and '511 patents pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and § 314.94(a)(12)(i)(A)(4) of Title 21 of the CFR in support of its ANDA. Aurobindo denies any remaining allegations in this paragraph.

60. Upon information and belief, Aurobindo had knowledge of the '714 and '511 Patents at least when it submitted ANDA No. 219349 to the FDA.

ANSWER: Paragraph 60 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Aurobindo Pharma admits it had knowledge of the '714 and '511 patents as of the date it submitted paragraph IV certifications for those patents. Aurobindo denies any remaining allegations of this paragraph.

> 61. Upon information and belief, Aurobindo intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Aurobindo ANDA Product immediately and imminently upon approval of ANDA No. 219349 and prior to the expiration of the '714 and '511 Patents.

ANSWER: Paragraph 61 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Aurobindo Pharma's filing of an ANDA with the FDA is merely a technical act of infringement and does not carry with it any implications of infringement, contributory infringement, or inducement of infringement under 35 U.S.C. § 271(a), (b), and/or (c). Aurobindo denies any remaining allegations of this paragraph.

> 62. On or before May 3, 2024, pursuant to an Offer of Confidential Access, Aurobindo produced portions of its ANDA No. 219349 to Esperion. Aurobindo refused to produce the entirety of ANDA No. 219349 to Esperion and refused to provide samples of its ANDA Product or components thereof.

ANSWER: Aurobindo admits that it promptly produced to Plaintiff certain portions of Aurobindo's ANDA pursuant to the terms of the mutually agreed Offer of Confidential Access to Portions of the ANDA No. 219349, dated May 1, 2024. Aurobindo denies any remaining allegations of this paragraph.

> 63. This action was commenced by the filing of a complaint on May 22, 2024, which was before the expiration of forty-five days from the date of Esperion's receipt of the First Notice Letter.

ANSWER: Paragraph 63 contains legal conclusions to which no answer is required. To the extent that Aurobindo is required to answer, Aurobindo admits that Plaintiff commenced this action on May 22, 2024. Except as expressly admitted, Aurobindo is without knowledge or

information sufficient to form a belief about the truth of the allegations in Paragraph 63, and on that basis denies these allegations.

64. On or about March 12, 2024, the U.S. Patent and Trademark Office issued the '584 Patent.

ANSWER: Aurobindo admits that the front page of the '584 Patent indicates the issue date of March 12, 2024.

65. On or about April 9, 2024, and within thirty days of issuance, Esperion submitted Form 3542 identifying the '584 patent for listing in the Orange Book for NEXLETOL®.

ANSWER: Aurobindo is without knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 65, and on that basis denies these allegations.

66. On information and belief, at some point on or after April 9, 2024, during the pendency of Aurobindo's ANDA, Aurobindo provided to the FDA a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '584 Patent.

ANSWER: Admitted.

67. By letter dated June 6, 2024, and received by Esperion via Federal Express no earlier than on June 7, 2024 (the "Second Notice Letter"), Aurobindo sent written notice to Esperion of its Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '584 Patent. In the Second Notice Letter, Aurobindo contended that the '584 Patent is invalid, unenforceable or will not be infringed by the commercial manufacture, use, and/or sale of the Aurobindo ANDA Product.

ANSWER: Paragraph 67 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Aurobindo Pharma admits that on June 6, 2024, it sent a Notice Letter to Esperion Therapeutics, Inc. pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 notifying Esperion that it had filed a patent certification with respect to the'584 patent pursuant to § 505(j)(2)(A)(vii)(IV) of the Act and § 314.94(a)(12)(i)(A)(4) of Title 21 of the CFR in support of its Abbreviated New Drug Application ("ANDA"). Aurobindo denies any remaining allegations in this paragraph.

68. Upon information and belief, Aurobindo had knowledge of the '584 Patent at least as of April 9, 2024, and certainly before June 6, 2024.

ANSWER: Paragraph 68 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Aurobindo Pharma admits that it had knowledge of the '584 patent as of June 6, 2024. Aurobindo denies any remaining allegations in this paragraph.

69. Upon information and belief, Aurobindo intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Aurobindo ANDA Product immediately and imminently upon approval of ANDA No. 219349 and prior to expiration of the '584 Patent.

ANSWER: Paragraph 69 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Aurobindo Pharma's filing of an ANDA with the FDA is merely a technical act of infringement and does not carry with it any implications of infringement, contributory infringement, or inducement of infringement under 35 U.S.C. § 271(a), (b), and/or (c). Aurobindo denies any remaining allegations of this paragraph.

70. This First Amended Complaint is being filed before the expiration of the forty-five days from the date of Esperion's receipt of the Second Notice Letter and prior to Aurobindo's answer to the original complaint filed May 22, 2024.

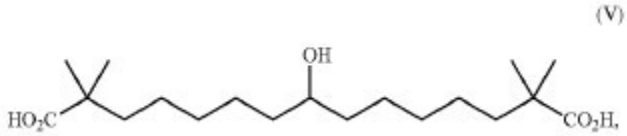
ANSWER: Paragraph 70 contains legal conclusions to which no answer is required. To the extent that Aurobindo is required to answer, Aurobindo admits that Plaintiff commenced this action on May 22, 2024. Except as expressly admitted, Aurobindo is without knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 70, and on that basis denies these allegations.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 11,760,714

71. Esperion incorporates each of the preceding paragraphs 1-70 as if fully set forth herein.

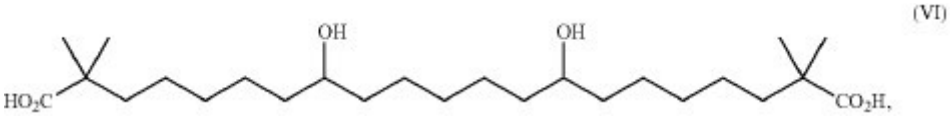
ANSWER: Aurobindo incorporates each of its answers to the preceding paragraphs 1-70.

72. Claim 1 of the '714 Patent requires a pharmaceutical composition, comprising: a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 98% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):

and a pharmaceutically acceptable excipient.



ANSWER: Paragraph 72 contains legal conclusions to which no answer is required.

73. Aurobindo's submission of ANDA No. 219349 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Aurobindo ANDA Product before the expiration of the '714 Patent constituted an act of infringement of the claims of the '714 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

74. Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation of the Aurobindo ANDA Product prior to expiration of the '714 Patent, and Aurobindo's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '714 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

75. Upon information and belief, upon FDA approval of ANDA No. 219349, Aurobindo intends to, and will, infringe at least claim 1 of the '714 Patent under

35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Aurobindo ANDA Product, unless enjoined by the Court.

ANSWER: Denied.

76. Upon information and belief, by virtue of its listing in the Orange Book and identification in Aurobindo's First Notice Letter, Aurobindo has knowledge of the '714 Patent and knowledge that its Aurobindo ANDA Product will infringe the '714 Patent.

ANSWER: Denied.

77. Upon information and belief, Aurobindo intends to, and will, actively induce infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(b) when ANDA No. 219349 is approved by marketing the Aurobindo ANDA Product and encouraging doctors and patients to infringe the '714 Patent, unless enjoined by the Court.

ANSWER: Denied.

78. Upon information and belief, Aurobindo intends to, and will, contribute to infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(c) when ANDA No. 219349 is approved, unless enjoined by the Court, because Aurobindo knows that the Aurobindo ANDA Product is especially made or adapted for use in infringing the '714 Patent, and that the Aurobindo ANDA Product is not suitable for substantial noninfringing use.

ANSWER: Denied.

79. Aurobindo's infringement is imminent because, among other things, Aurobindo has notified Esperion of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Aurobindo ANDA Product before the expiration of the '714 Patent.

ANSWER: Denied.

80. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '714 Patent.

ANSWER: Paragraph 80 of the Complaint states a legal conclusion to which no response is required. Aurobindo admits that there exists a substantial and justiciable controversy between the parties regarding Aurobindo's alleged infringement of the '714 patent. Aurobindo

denies that it has infringed the '714 patent. Aurobindo denies any remaining allegations of this paragraph.

81. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Aurobindo's making, using, offering to sell, selling, and/or importing the Aurobindo ANDA Product, inducement thereof or contribution thereto, will infringe the '714 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

82. Unless Aurobindo is enjoined from directly or indirectly infringing the '714 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

ANSWER: Denied.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 11,613,511

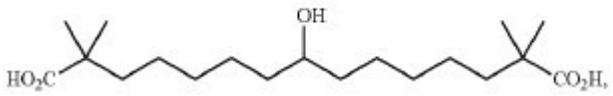
83. Esperion incorporates each of the preceding paragraphs 1-82 as if fully set forth herein.

ANSWER: Aurobindo incorporates each of its answers to the preceding paragraphs 1-82.

84. Claim 1 of the '511 Patent requires a pharmaceutical material comprising a crystalline form of the compound of formula (V):

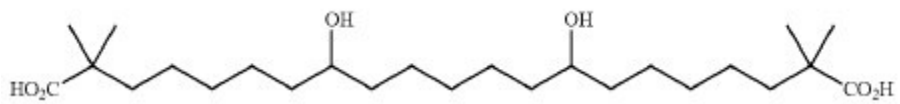
or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical

(V)



material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, the pharmaceutical material

(VI)



comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):
and the crystalline form of the compound of formula (V) exhibits an X-ray powder diffraction pattern comprising peaks at the following diffraction angles (2θ): 10.3±0.2, 10.4±0.2, 17.9±0.2, 18.8±0.2, 19.5±0.2, and 20.7±0.2.

ANSWER: Paragraph 84 contains legal conclusions to which no answer is required.

85. Aurobindo's submission of ANDA No. 219349 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Aurobindo ANDA Product before the expiration of the '511 Patent constituted an act of infringement of the claims of the '511 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

86. Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation of the Aurobindo ANDA Product prior to expiration of the '511 Patent, and Aurobindo's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '511 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

87. Upon information and belief, upon FDA approval of ANDA No. 219349, Aurobindo intends to, and will, infringe at least claim 1 of the '511 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Aurobindo ANDA Product, unless enjoined by the Court.

ANSWER: Denied.

88. Upon information and belief, by virtue of its listing in the Orange Book and identification in Aurobindo's First Notice Letter, Aurobindo has knowledge of the '511 Patent and knowledge that its Aurobindo ANDA Product will infringe the '511 Patent.

ANSWER: Denied.

89. Upon information and belief, Aurobindo intends to, and will, actively induce infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(b) when ANDA No. 219349 is approved by marketing the Aurobindo ANDA Product and encouraging doctors and patients to infringe the '511 Patent, unless enjoined by the Court.

ANSWER: Denied.

90. Upon information and belief, Aurobindo intends to, and will, contribute to infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(c)

when ANDA No. 219349 is approved, unless enjoined by the Court, because Aurobindo knows that the Aurobindo ANDA Product is especially made or adapted for use in infringing the '511 Patent, and that the Aurobindo ANDA Product is not suitable for substantial noninfringing use.

ANSWER: Denied.

91. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '511 Patent.

ANSWER: Paragraph 91 of the Complaint states a legal conclusion to which no response is required. Aurobindo admits that there exists a substantial and justiciable controversy between the parties regarding Aurobindo's alleged infringement of the '511 patent. Aurobindo denies that it has infringed the '511 patent. Aurobindo denies any remaining allegations of this paragraph.

92. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Aurobindo's making, using, offering to sell, selling, and/or importing the Aurobindo ANDA Product, inducement thereof or contribution thereto, will infringe the '511 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

93. Unless Aurobindo is enjoined from directly or indirectly infringing the '511 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

ANSWER: Denied.

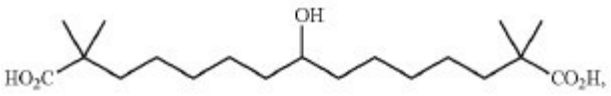
COUNT III: INFRINGEMENT OF U.S. PATENT NO. 11,926,584

94. Esperion incorporates each of the preceding paragraphs 1-93 as if fully set forth herein.

ANSWER: Aurobindo incorporates each of its answers to the preceding paragraphs 1-93.

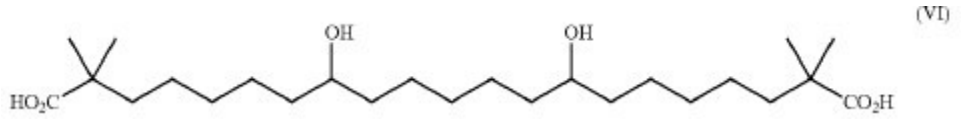
95. Claim 1 of the '584 Patent claims a method of lowering low-density

(V)



lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):

or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than
99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



(VI)

ANSWER: Paragraph 95 contains legal conclusions to which no answer is required.

96. Aurobindo's submission of ANDA No. 219349 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Aurobindo ANDA Product before the expiration of the '584 Patent constituted an act of infringement of the claims of the '584 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

97. Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation of the Aurobindo ANDA Product prior to expiration of the '584 Patent, and Aurobindo's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '584 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (b), and/or (c).

ANSWER: Denied.

98. Upon information and belief, upon FDA approval of Aurobindo's ANDA No. 219349, Aurobindo will infringe at least claim 1 of the '584 Patent by making, using, offering to sell, and selling the Aurobindo ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '584 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

ANSWER: Denied.

99. Upon information and belief, Aurobindo specifically intends to, and will, actively induce infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(b) when ANDA No. 219349 is approved by marketing the Aurobindo ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '584 Patent, unless enjoined by the Court.

ANSWER: Denied.

100. Upon information and belief, Aurobindo' ANDA No. 219349 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Aurobindo ANDA Product.

ANSWER: Denied.

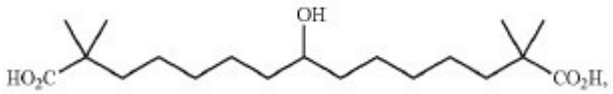
101. Upon information and belief, upon FDA approval of ANDA No. 219349, Aurobindo intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the Aurobindo ANDA Product, unless enjoined by the Court, and the Aurobindo ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

ANSWER: Denied.

102. On information and belief, the proposed package insert will include a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):

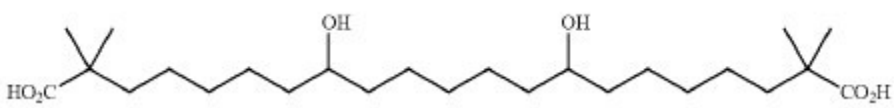
or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically

(V)



acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material

(VI)



comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):

ANSWER: Denied.

103. Upon information and belief, the use of the Aurobindo ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the '584 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Denied.

104. Upon information and belief, by virtue of its listing in the Orange Book and identification in Aurobindo's Second Notice Letter, Aurobindo has knowledge of the '584 Patent and knowledge that its Aurobindo ANDA Product will infringe the '584 Patent.

ANSWER: Denied.

105. On information and belief, Aurobindo is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the Aurobindo ANDA Product at least according to Aurobindo's proposed package insert and, therefore, will directly infringe at least claim 1 of the '584 Patent.

ANSWER: Denied.

106. Upon information and belief, Aurobindo intends to, and will, contribute to infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(c) when ANDA No. 219349 is approved, unless enjoined by the Court, because Aurobindo knows that the Aurobindo ANDA Product is especially made or adapted for use in infringing the '584 Patent, and that the Aurobindo ANDA Product is not suitable for substantial noninfringing use.

ANSWER: Denied.

107. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '584 Patent.

ANSWER: Paragraph 107 of the Complaint states a legal conclusion to which no response is required. Aurobindo admits that there exists a substantial and justiciable controversy between the parties regarding Aurobindo's alleged infringement of the '584 patent. Aurobindo denies that it has infringed the '584 patent. Aurobindo denies any remaining allegations of this paragraph.

108. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Aurobindo's making, using, offering to sell, selling, and/or importing the Aurobindo ANDA Product, inducement thereof or contribution thereto, will infringe the '584 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(b) and/or (c).

ANSWER: Denied.

109. Unless Aurobindo is enjoined from directly or indirectly infringing the '584 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

ANSWER: Denied.

RESPONSE TO REQUEST FOR RELIEF

Aurobindo denies that Plaintiff is entitled to any of the relief sought in their request for relief.

AUROBINDO'S AFFIRMATIVE DEFENSES

An allegation of any defense below is not an admission that Aurobindo bears the burden of proof or persuasion on any claim or issue.

First Affirmative Defense - Non-Infringement

Aurobindo has not infringed, is not infringing, will not infringe, will not induce to infringe, and will not contribute to infringement of, literally or under the doctrine of equivalents, any valid and enforceable claim of the '714, '511, and '584 patents.

Second Affirmative Defense – Invalidity or Unenforceability

The claims of the '714, '511, and '584 patents are invalid and/or unenforceable for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation, one or more of 35 U.S.C. §§ 101, 102, 103, 112, and 116 and/or for double patenting or for failure to satisfy other judicially created bases for invalidity or unenforceability.

Third Affirmative Defense – Prosecution History Estoppel

Plaintiff's claims are barred, in whole or in part, by the doctrine of prosecution history estoppel. The claims of the '714, '511, and '584 patents against Aurobindo are so limited as not to cover the manufacture, use, sale, offer for sale, or importation of the proposed ANDA products described in Aurobindo's ANDA due to the arguments, statements, representations and/or amendments made by Plaintiff to the United States Patent and Trademark Office during the prosecution of the applications leading to issuance of the '695 patent.

Fourth Affirmative Defense – Failure to State a Claim

Plaintiff's Complaint fails to state a claim upon which relief can be granted.

Fifth Affirmative Defense – Failure to State a Claim For Exceptional Case

Plaintiff's Complaint fails to state a claim for exceptional case under 35 U.S.C. § 285 and/or willful infringement. Aurobindo's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

RESERVATION OF ADDITIONAL DEFENSES

Aurobindo reserves the right to assert such other defenses and damages, if such defenses or and damages are discovered during the course of this litigation.

AUROBINDO'S PRAYER FOR RELIEF

WHEREFORE, Aurobindo respectfully prays that this Court enter judgment in Aurobindo's favor and grant the following relief:

A. Dismiss Plaintiff's Complaint with prejudice and deny each and every prayer for relief contained therein;

B. A declaration that Aurobindo does not infringe the claims of the Asserted Patents;

C. A declaration that the claims of the Asserted Patents are invalid or unenforceable;

D. Award the costs of this action against Plaintiff;

E. A declaration that this is an exceptional case within the meaning of 35 U.S.C. § 285, and that Aurobindo is entitled to recover reasonable attorney fees and costs upon prevailing in this action;

F. A declaration that the effective date of any FDA approval of Aurobindo's proposed ANDA product shall not be stayed thirty months from the date of its Notice Letters, in accordance with 21 U.S.C. § 355(j)(5)(B)(iii);

G. An award to Aurobindo of such further and other relief as this Court deems necessary, just, and proper.

Date: July 11, 2024

/s/ Dmitry Shelhoff

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that, upon information and belief, the matter in controversy is not the subject of any other action pending against Aurobindo in any other court, or any pending arbitration or administrative proceeding, but appears at the time of this certification to be related to the following actions in the District of New Jersey: *Esperion Therapeutics, Inc. v. Micro Labs USA, Inc.*, 24-cv-05921 (JXN) (CLW) (D.N.J.); *Esperion Therapeutics, Inc. v. Renata Limited*, 24-cv-06017 (JXN) (CLW) (D.N.J.); *Esperion Therapeutics, Inc. v. Accord Healthcare, Inc.*, 24-cv-06224 (JXN) (CLW) (D.N.J.); *Esperion Therapeutics, Inc. v. Alkem Laboratories Ltd.*, 24-cv-06224 (JXN) (CLW) (D.N.J.); *Esperion Therapeutics, Inc. v. Dr. Reddy's Laboratories, Inc.*, 24-cv-06391 (JXN) (CLW) (D.N.J.); *Esperion Therapeutics, Inc. v. Hetero USA Inc. et al.*, 24-cv-06389 (JXN) (CLW) (D.N.J.); *Esperion Therapeutics, Inc. v. Sandoz Inc.*, 24-cv-06387 (JXN) (CLW) (D.N.J.); and *Esperion Therapeutics, Inc. v. MSN Pharmaceuticals, Inc. et al.*, 24-cv-06386 (JXN) (CLW) (D.N.J.).

Date: July 11, 2024

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CERTIFICATE OF SERVICE

I, Dmitry V. Shelhoff, certify that on July 11, 2024, I caused a true and correct copy of DEFENDANTS AUROBINDO PHARMA LIMITED AND APITORIA PHARMA PRIVATE LIMITED'S ANSWER TO FIRST AMENDED COMPLAINT FOR PATENT INFRIGEMENT and CERTIFICATION PURSUANT TO L. CIV. R. 11.2 to be served via ECF to the following counsel of record:

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